CLINICAL DEPARTMENT

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believe in life

AGENDA

ROLE OF CLINICAL DPT WITHIN THE PHARMACEUTICAL INDUSTRY

ONE DAY IN THE OFFICE

WHAT IS THE MARKED LOOKING FOR?

ARE YOU THE RIGHT PROFILE?

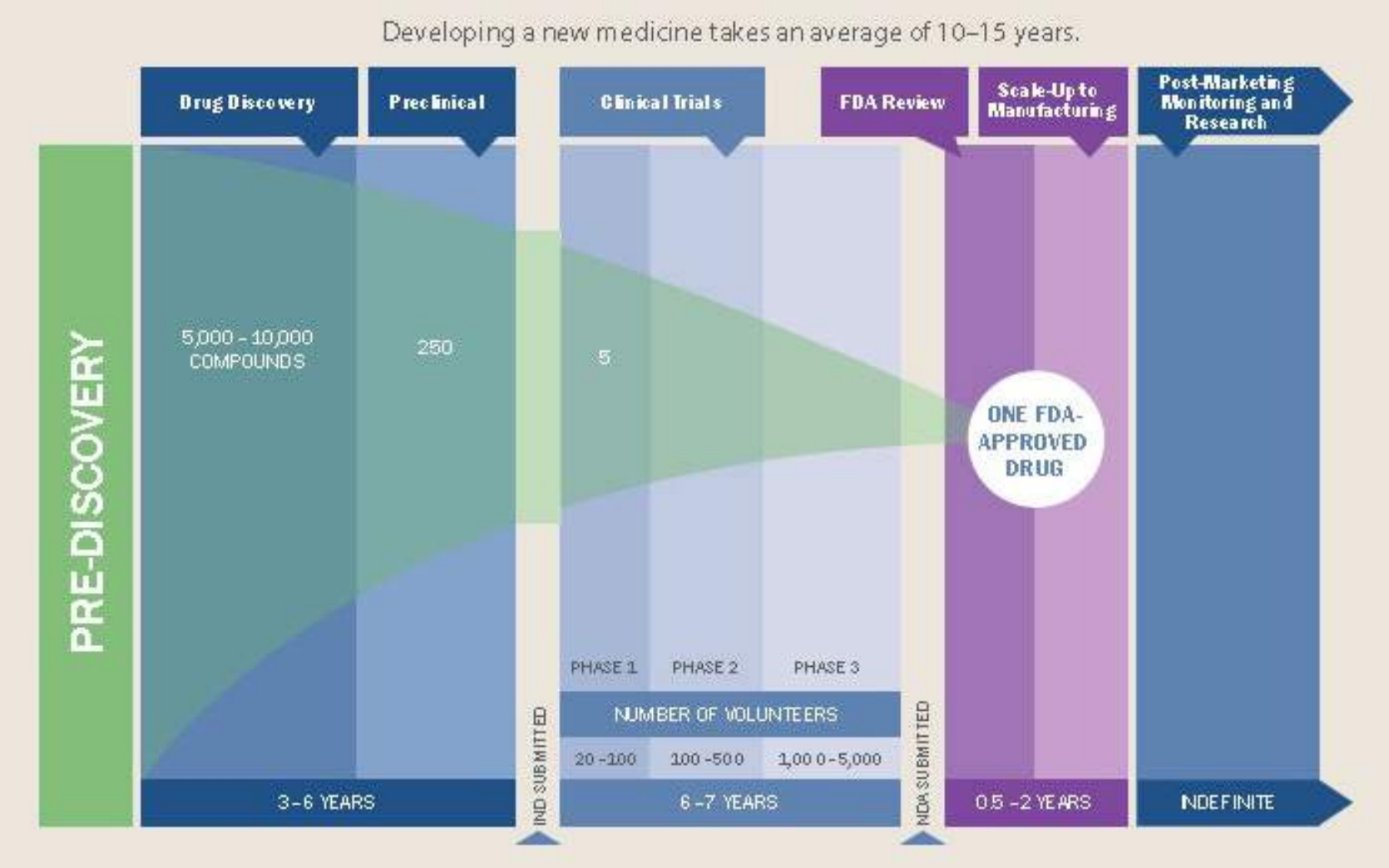
CARRER DEVELOPMENT

ROLE OF CLINICAL WITHIN THE PHARMACEUTICAL INDUSTRY

- Clinical Department is involved from the beginning of the development until the approval of the drug product.

It is crucial to define the clinical strategy and the design of all the clinical studies in order to obtain the approval around the world.

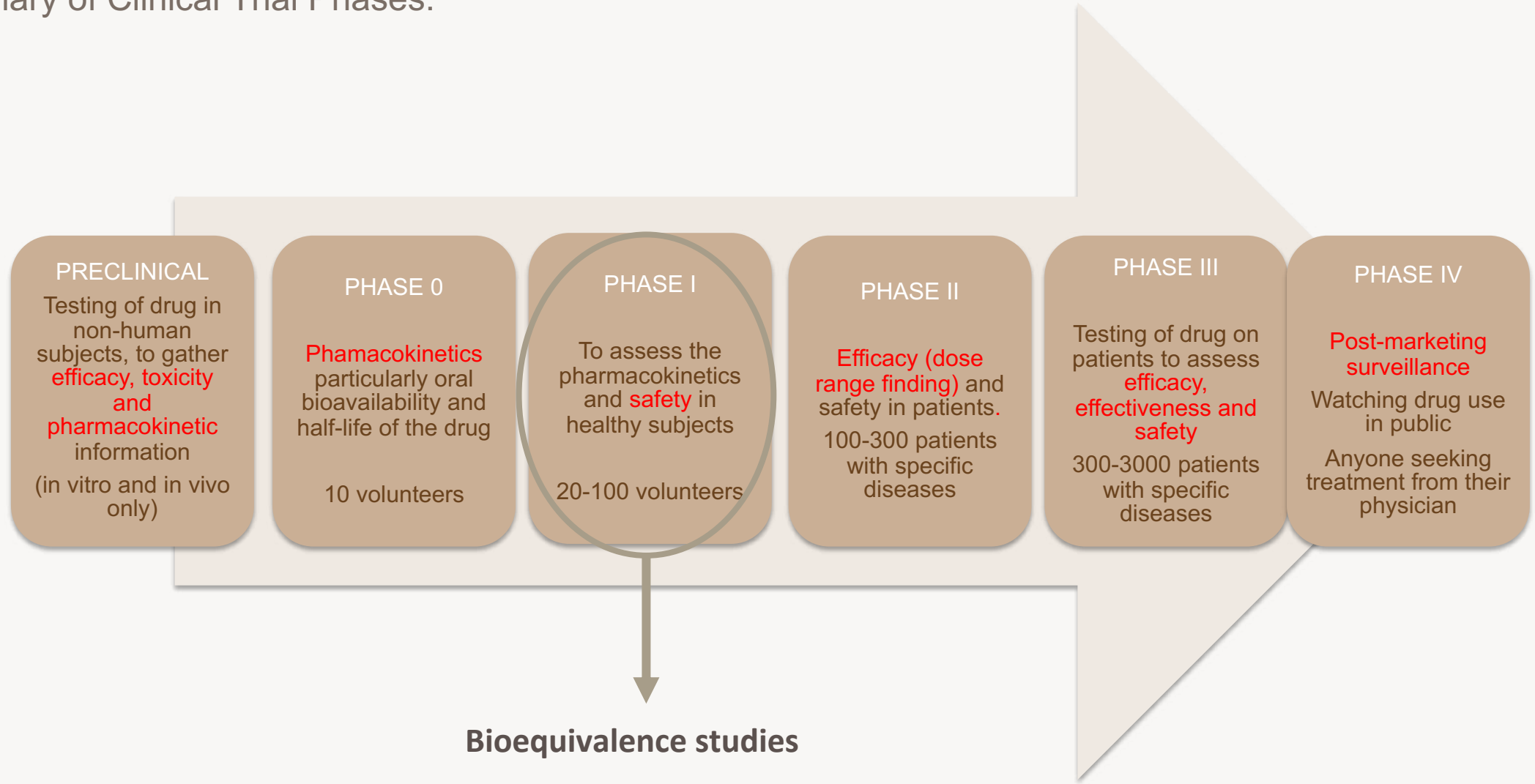
ROLE OF CLINICAL WITHIN THE PHARMACEUTICAL INDUSTRY



Pharmaceutical Research and Manufacturers of America, Drug Discovery and Development (www.innovation.org)

ROLE OF CLINICAL WITHIN THE PHARMACEUTICAL INDUSTRY

- Summary of Clinical Trial Phases:



ONE DAY IN THE OFFICE

Characteristics

Dynamism
Flexibility
No suitable for routine lovers
High pressure: TIME IS MONEY

Tasks

- Email
- Inter/Intra departmental meetings (new and follow-up projects)
- Negotiation cost
- Bibliographical research
- Clinical study design
- Be updated with the current legislation

ONE DAY IN THE OFFICE

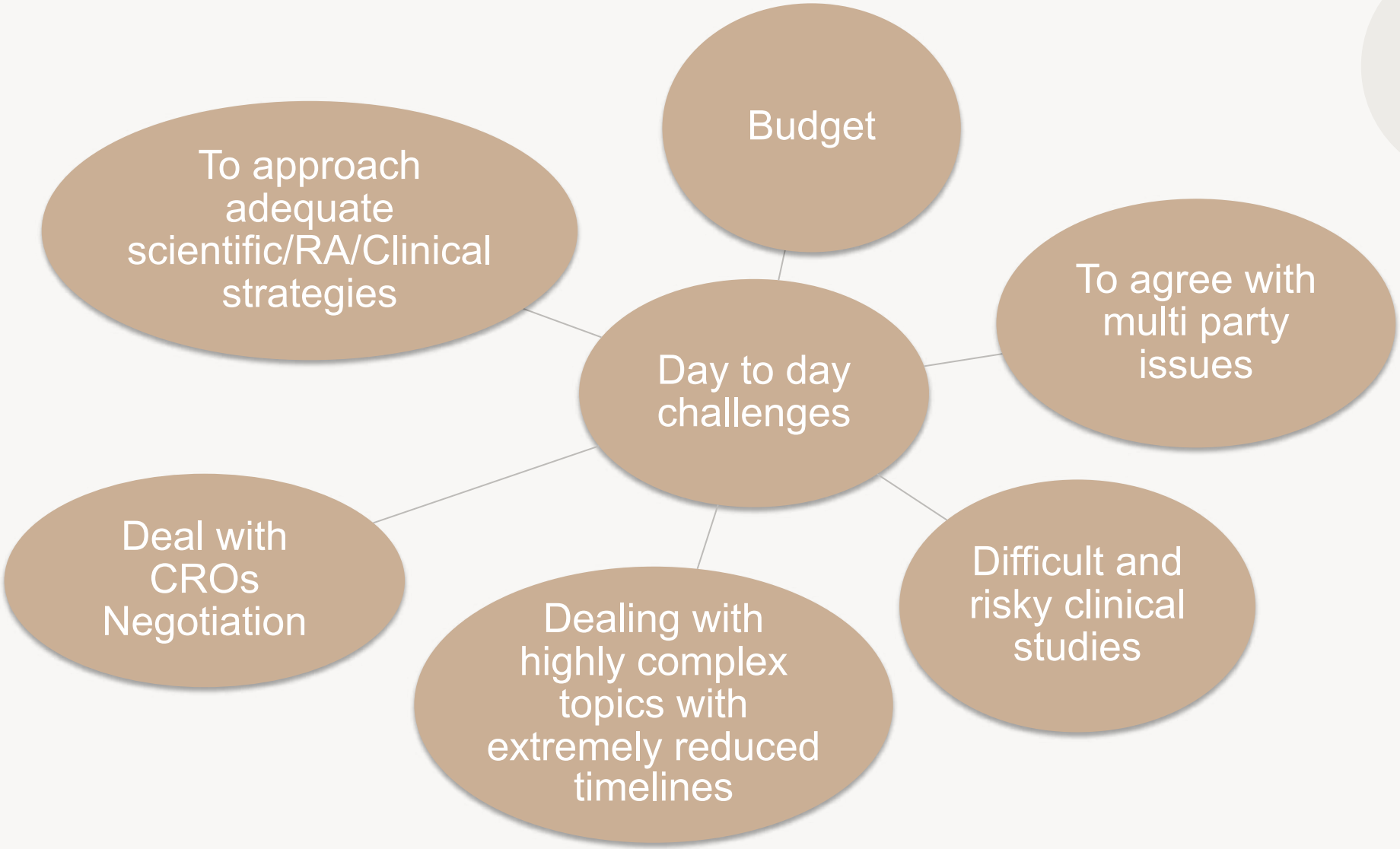
- Investigator/monitor selection
- Revision of Protocol/ Informed consent/ Case Report form/ Investigator brochure (IB)
- Ethics Committee and Health Authorities approval
- Provide drug study medication
- Submit any serious adverse event occurred during study
- Provide insurance to patients participants
- Collection and Analysis of patient data
- Revision of Clinical & Analytical Final Reports
- Complilation of Module 5 of the Dossier
- Responses to Letters of Defficiency from Regulatory Authorities
- Feasibilities for new projects and clinical justifications

HIGH RESPONSABILITY

ONE DAY IN THE OFFICE

- **Interdepartamental connections**

ONE DAY IN THE OFFICE



WHAT IS THE MARKET LOOKING FOR

- Highly responsible, proactive, dynamic, methodical, decisive and organized individual.
- Excellent oral and written communication and interpersonal skills.
- Strong analytical frame of mind and problem solving.
- Capable to work under pressure.
- Strong organizational and time management skills.

Teamworking is the most important one to comply our goals.

ARE YOU THE RIGHT PROFILE

DEGREE:

- Health Sciences, preferably Pharmacy, but also: Chemistry, Biochemistry, biotechnology, Medicine, etc)
- Desirable post-graduate focused in Industry, including internship. Ex: CESIF, UB, etc.
- High level of English (both Oral and written communication)

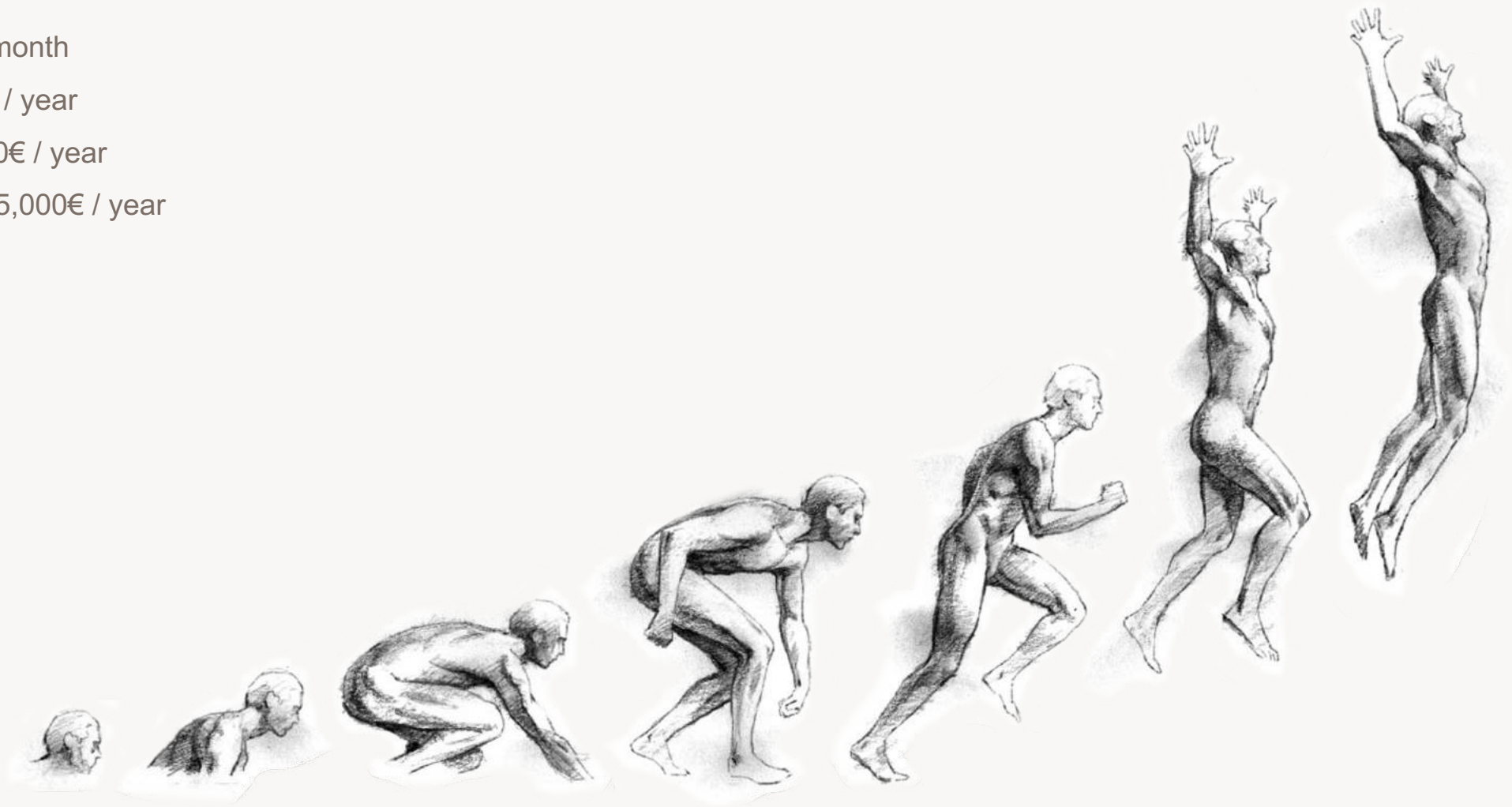
PROFESSIONAL EXPERIENCE:

- Clinical affairs
- Biopharmaceutics
- Clinical and non-clinical development
- Monitoring (CRA)
- Clinical operations
- Bioanalytical
- Statistical databases management
- Medical Affairs / Advisor

CARRER DEVELOPMENT

Clinical Department:

- Internship: 600-1000€/month
- Junior: 20,000-30,000€ / year
- Senior 1: 30,000-45,000€ / year
- Senior 2 (>8 years): >45,000€ / year



THANK **YOU**

KAHOOT – CLINICAL DEPARTMENT

Which are the clinical trial phases?

1. Phase I, Phase II, Phase III
2. Preclinical and Phase 0
3. Phase I, Phase II, Phase III, Phase IV
4. Preclinical, Phase 0, Phase I, Phase II, Phase III, Phase IV

Which are some of the clinical department responsibilities?

1. Prepare the budget
2. Deal with CROs negotiation
3. To approach adequate scientific/RA/Clinical strategies for each project
4. All above are correct